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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/726,486 | 12/04/2003 | Yuji Ishihara | 2003_1747 | 7546 |

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EXAMINER

TRUONG, TAMTHOM NGO

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/726,486

Applicant(s)

ISHIHARA ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8-8-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FINAL ACTION

Applicant's amendment of 5-22-06 has been fully considered. The amended claim 26 has overcome the previous rejection of 102 based on **Kawakita et. al.** (US'039), and thus, said rejection is now withdrawn. However, applicant's argument has not overcome the previous rejection of 103, and so, it is maintained herein.

Claims 1-25 and 27 are cancelled.

Claims 26, 28 and 29 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 26, 28 and 29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the following references in view of **Tobin et. al.** and **Lai et. al.**:

a. **Pang et. al.** (US 5,783,584): On column 1, Pang et. al. disclose the second compound (or 9-amino-1,2,3,4-tetrahydroacridine, commercially known as COGNEX) of the instant claim 26;

- b. **Yu et. al.** (US 5,177,082 – cited on IDS): On column 16, Yu et. al. disclose a compound in Example 1 (or Huperzine A) which reads on the third compound of the instant claim 26.
- c. **Renko et. al.** (US 5,958,903): On column 1, Renko et. al. disclose a galanthamine compound (commercially known as NIVALINETM) that reads on the fourth compound of the instant claim 26.

The above references associate the disclosed compounds with acetylcholinesterase inhibitors. However they differ from the instant claim 27 by applying those compounds to the treatment of Alzheimer's disease, dementia or myasthenia gravis (as in the case of Huperzine A). Such a difference can be overcome by the teaching of **Tobin et. al.** and **Lai et. al.**

Tobin et. al. identify three acetylcholine (or muscarinic) receptors that affect a bladder, namely: M₁, M₂, and M₃. Lai et. al. further reveal that : “*activation of M₂ receptor indirectly contributes to bladder contraction...*”. Therefore, from the relationship of muscarinic receptors with urinary bladder taught by Tobin et. al. and Lai et. al., the skilled medicinal chemist would have been motivated to treat *dysuria* (as recited in the instant claims 28 and 29) by *improving excretory potency* with a *cholinesterase inhibitor* (as recited in the instant claim 26) such as those disclosed by Pang et. al., Yu et. al., or Renko et. al.

Applicants contended “there would have been no reasonable expectation of success by one of ordinary skill in the art of the claimed method from the cited references.” However, applicants did not cite rationales for “no reasonable expectation of success” In reviewing the reference of **Yu et. al.** (disclosing Huperzine A), it is noted that said compound can also treat

myasthenia gravis which indicates an increase in muscle contraction (e.g., see column 5, line 5). Likewise, in US '903, **Renko et. al.** mention the activity of cholinesterase inhibitors in the maintenance of muscle force in patient suffering from myasthenia gravis (see column 1, lines 10-15). Thus, it is rather well known in the art that **cholinesterase inhibitors increase muscle contraction**. Such a fact combining with the finding of Tobin et. al. and Lai et. al. would have lead to "reasonable expectation of success".

It is maintained that at the time that the invention was made, it would have been obvious to develop a method as claimed herein in view of the combined teachings above.

Reference cited on PTO-892

An update search yields the reference of **Murray et. al.** (WO 99/08672) which discloses all four compounds of claim 26. However, said compounds are used in the treatment of arthritis.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

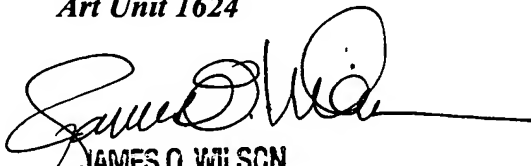
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Tamthom N. Truong
Examiner
Art Unit 1624

8-29-06


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